

REMARKS

This Amendment is filed in response to the Official Action mailed November 16, 2006. In this Amendment, claims 44, 69, 89, 99 and 100 are amended and claims 45-47, 54-56, 60-61, 64-68, 76-77, 81-85, 87-88 and 90-98 are unchanged. Claims 59, 70-75, 78-80 and 86 remain withdrawn. Following entry of this amendment, claims 44-47, 54-56, 59-61 and 64-100 shall be pending.

In the Office Action, claims 99 and 100 are objected to because of an informality, and claims 44-47, 54-56, 60, 61, 64-69, 76, 77 and 87-94 have been rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. CLAIM OBJECTION

The Examiner objected to claims 99 and 100 because the preamble for these claims recited an apparatus but depended from a method claim. Claims 99 and 100 have been amended to recite a "method" and to depend from claim 98. Therefore it is requested that the objection to these claims be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. SECTION 102

Claims 44-47, 54-56, 60, 61, 64, 67-69, 76, 77 and 87-91 are rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,234,456 to Silvestrini (*The Silvestrini et al. Patent*). For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Turning to claim 44, this claim is directed to an apparatus that is implantable in the vasculature of a subject to treat a vascular aneurysm, said apparatus, comprising at least one expandable stent having fenestrations, said expandable stent comprising a substantially cylindrical body member located between first and second ends, said cylindrical body member having at least one circumferential element between said first and said second ends defining an internal lumen in communication with said first and second ends; wherein said at least one expandable stent is expandable between a first

diameter D and a second diameter D' wherein D' is larger than D; and a reactive material on a portion of the stent, said reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation resulting in expansion of the reactive material and resulting in a decrease in the size of some of the fenestrations such that blood flow through those fenestrations is lessened.

The Silvestrini et al. Patent cannot be properly relied upon as anticipating the invention as recited in claim 44. For example, *the Silvestrini et al. Patent* fails to at least show a reactive material on a portion of the stent, said reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body as claimed. As seen best in column 2 lines 38-47, *the Silvestrini et al. Patent* discloses the use of a hydrogel (or similar substances) that only absorbs or attracts a liquid:

The stent 10 has disposed within its hollow wall 12 a hydrophilic material 32 which is capable of absorbing or attracting a liquid via osmotic dilution to thereby increase the volume of or pressure exerted by material 32. This hydrophilic material 32 can be any bio-compatible agent that will drive an osmotic pressure. Examples include, but are not limited to, inorganic salts, organic salts, sugars, poly saccharides, polymeric hydrogels, or amphoteric molecules. One preferred material is a hydrogel such as polyvinyl alcohol.

In this respect, the substance of *the Silvestrini et al. Patent* may expand in liquid, but will not have at least a first and second state of protonation as recited in claim 44.

To further appreciate this distinction, the Examiner is directed to the contents of U.S. Patent Application No. 2002/0176880 which is discussed and incorporated by reference in paragraphs 0044 and 0048 of the present Application. More specifically, the Examiner is directed to paragraph 0006 of application 2002/0176880 which provides examples of the claimed reactive material:

For example, if acrylic acid is incorporated into the crosslinked network, the hydrogel is incubated in a low pH solution to protonate the carboxylic acids. After the excess low pH solution has been rinsed away and the hydrogel dried, the hydrogel can be introduced through a microcatheter filled with saline at physiological pH or blood. **The hydrogel cannot expand until the carboxylic acid groups deprotonate.** Conversely, if an amine containing monomer is incorporated into the crosslinked network, the hydrogel is incubated in a high pH solution to deprotonate amines. After the excess high pH solution has been rinsed away and the hydrogel dried, the hydrogel can be introduced through a microcatheter filled with saline at physiological pH or blood. **The hydrogel cannot expand until the amine groups protonate.** [Emphasis added]

As previously emphasized in the Response to Office Action dated February 24, 2006, the hydrogels and similar materials in the cited prior art do not routinely protonate and deprotonate as recited in claim 44. By way of example, the specification of the present Application describes a reactive material that will undergo protonation when it comes into contact with blood at physiological pH and will then result in expansion, as claimed. Thus, in some examples, the expansion of the reactive material (e.g., hydrogel) can be delayed until a period of time after implantation.

Therefore in view of the above, even if *the Silvestrini et al. Patent* discloses materials that absorb water, the undersigned can find no disclosure in *Silvestrini et al.* to suggest that these materials undergo a change in protonation as recited in claim 44. Thus, for at least this reason, *the Silvestrini et al. Patent* fails to anticipate claim 44. It is also submitted that *the Silvestrini et al. Patent* does not render claim 44 obvious.

Claims 45-47, 54-56, 59-61, 64-68 and 87-88 depend from claim 44 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

Turning to claim 69, this claim is directed to an apparatus for treating vascular aneurysms, comprising: at least one expandable, woven stent having fenestrations, said expandable stent further having a cylindrical body member located between a first and second end, said cylindrical body member further defining an internal lumen in communication with said first and second ends, wherein blood is capable of flowing through said internal lumen and flowing radially through said fenestrations into the aneurysm; wherein said at least one expandable stent is expandable between a first D and a second D' wherein D' is larger than D; and a pH reactive material interwoven with said at least one expandable, woven stent, said pH reactive material having a non-reacted state and a reacted state, wherein said pH reactive material in said reacted state is capable of increasing the resistance to blood flow through not all of said fenestrations.

The Silvestrini et al. Patent cannot be properly relied upon as anticipating the invention as recited in claim 69. For example, *the Silvestrini et al. Patent* fails to at least show a pH reactive material interwoven with said at least one expandable, woven stent as claimed. As seen best in column 2 lines 38-47, *the Silvestrini et al. Patent* discloses the use of a hydrogel or similar materials that only absorbs or attracts a liquid. In contrast, the specification of the present Application describes a reactive material that will undergo a reaction when it comes into contact with blood at physiological pH and will then result in expansion, as claimed. Thus, in some examples, the expansion of the reactive material (e.g., hydrogel) can be delayed until a period of time after implantation.

The undersigned is unable to find any discussion in *the Silvestrini et al. Patent* of the use of a pH reactive material as recited in claim 69. Further, even if *the Silvestrini et al. Patent* discloses materials that absorb water, the undersigned can find no disclosure in *Silvestrini et al.* suggesting that these materials must undergo a reaction from pH as recited in claim 69. Thus, for at least this reason, *the Silvestrini et al. Patent* fails to anticipate claim 69. It is also submitted that *the Silvestrini et al. Patent* does not render claim 69 obvious.

Turning to claim 76, this claim is directed to an apparatus that is implantable in the vasculature of a subject to treat a vascular aneurysm, said apparatus comprising a helical stent that is expandable from a first diameter D to a second diameter D', wherein D' is larger than D, said helical stent having an external surface and an internal lumen when expanded to its second diameter D' and there being at least one opening through said external surface; and a reactive material on a portion of said helical stent, said reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation giving rise to expansion of the reactive material and resulting in a decrease in the size of at least one opening such that blood flow through said at least one opening is lessened.

The Silvestrini et al. Patent cannot be properly relied upon as anticipating the invention as recited in claim 76. For example, *the Silvestrini et al. Patent* fails to at least show a reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation giving rise to expansion of the reactive material as claimed. As seen best in column 2 lines 38-47, *the Silvestrini et al. Patent* discloses the use of a hydrogel (or similar substance) that only absorbs or attracts a liquid to expand. In contrast, the specification of the present Application describes a reactive material that will undergo a reaction (protonation or deprotonation) when it comes into contact with blood at physiological pH and will then result in expansion, as claimed. Thus, in some examples, the expansion of the reactive material (e.g., hydrogel) can be delayed until a period of time after implantation.

The undersigned is unable to find any discussion of any material in *the Silvestrini et al. Patent* having a first and second state of protonation as recited in claim 76. Further, even if *the Silvestrini et al. Patent* discloses materials that absorb water, the undersigned can find no disclosure in *Silvestrini et al.* suggesting that these materials must undergo a change in protonation as recited in claim 76. To this end, the Examiner is again directed to the contents of U.S. Patent Application No. 2002/0176880

(incorporated by reference into the present application) which provides a further appreciation of this distinction. Thus, for at least this reason, *the Silvestrini et al. Patent* fails to anticipate claim 76. It is also submitted that *the Silvestrini et al. Patent* does not render claim 76 obvious.

Turning to claim 77, this claim is directed to an apparatus that is implantable in the vasculature of a subject to treat a vascular aneurysm, said apparatus, comprising an expandable reticulated stent having a substantially cylindrical body member located between a first and second end, said cylindrical body member having at least one circumferential element between said first and said second end defining an internal lumen in communication with said first and second ends, wherein blood is capable of flowing through said internal lumen and radially out of the Internal lumen through fenestrations and into the aneurysm; said cylindrical body member formed by a plurality of support members capable of supporting vascular tissue; said cylindrical body member having a first diameter D and a second diameter D', wherein D' is larger than D; and a reactive material selectively applied to some but not all of said of said support members, said reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation of giving rise to expansion of the reactive material and resulting in a decrease in the size of some of the fenestrations such that blood flow through those fenestrations is lessened.

The Silvestrini et al. Patent cannot be properly relied upon as anticipating the invention as recited in claim 77. For example, *the Silvestrini et al. Patent* fails to at least show a reactive material having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation of giving rise to expansion of the reactive material as claimed. As seen best in column 2 lines 38-47, *the Silvestrini et al. Patent* discloses the use of a hydrogel (or similar substance) that only absorbs or attracts a liquid to expand. In contrast, the specification of the present Application describes a reactive material that will undergo a reaction (protonation or deprotonation) when it

comes into contact with blood at physiological pH and will then result in expansion, as claimed. Thus, in some examples, the expansion of the reactive material (e.g., hydrogel) can be delayed until a period of time after implantation.

The undersigned is unable to find any discussion of any material in *the Silvestrini et al. Patent* having a first and second state of protonation as recited in claim 77. Further, even if *the Silvestrini et al. Patent* discloses materials that absorb water, the undersigned can find no disclosure in *Silvestrini et al.* suggesting that these materials must undergo a change in protonation as recited in claim 77. In this regard, the Examiner is again directed to the content of U.S. Patent Application No. 2002/0176880 (incorporated by reference in the present Application) which provides a further appreciation of this distinction. Thus, for at least this reason, *the Silvestrini et al. Patent* fails to anticipate claim 77. It is also submitted that *the Silvestrini et al. Patent* does not render claim 77 obvious.

Turning to claim 89, this claim is directed to an apparatus for treating vascular aneurysms, comprising at least one expandable stent having fenestrations, said expandable stent comprising a substantially cylindrical body member located between a first and second end, said cylindrical body member further defining an internal lumen in communication with said first and second ends, wherein blood is capable of flowing through said internal lumen and flowing radially through said fenestrations into the aneurysm; wherein said at least one expandable stent is expandable between a first diameter D and a second diameter D', wherein D' is larger than D; and a stimulus-expandable hydrogel selectively applied to the stent adjacent to some but not all of said fenestrations, said stimulus-expandable hydrogel having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body, said change in the state of protonation of giving rise to expansion of the reactive material and resultant lessening the size of some of the adjacent fenestrations such that blood flow through those fenestrations is lessened.

The Silvestrini et al. Patent cannot be properly relied upon as anticipating the invention as recited in claim 89. For example, *the Silvestrini et al. Patent* fails to at least

show a stimulus-expandable hydrogel having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body as claimed. As seen best in column 2 lines 38-47, *the Silvestrini et al. Patent* discloses the use of a hydrogel (or similar substance) that only absorbs or attracts a liquid to expand. In contrast, the specification of the present Application describes a reactive material that will undergo a reaction (protonation or deprotonation) when it comes into contact with blood at physiological pH and will then result in expansion, as claimed. Thus, in some examples, the expansion of the reactive material (e.g., hydrogel) can be delayed until a period of time after implantation.

The undersigned is unable to find any discussion of any material in *the Silvestrini et al. Patent* having a first and second state of protonation as recited in claim 89. Further, even if *the Silvestrini et al. Patent* discloses materials that absorb water, the undersigned can find no disclosure in *Silvestrini et al.* suggesting that these materials must undergo a change in protonation as recited in claim 89. Again, the Examiner is directed to the contents of U.S. Patent Application No. 2002/0176880 (incorporated by reference in the present Application) which provides a further appreciation of this distinction. Thus, for at least this reason, *the Silvestrini et al. Patent* fails to anticipate claim 89. It is also submitted that *the Silvestrini et al. Patent* does not render claim 89 obvious.

Claims 90-94 depend from claim 89 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

III. REJECTIONS UNDER 35 U.S.C. SECTION 103

Claims 65 and 66 are rejected under 35 U.S.C. Section 103(a) as being obvious by U.S. Patent No. 5,234,456 to Silvestrini (*The Silvestrini et al. Patent*) in view of U.S. Patent No. 5,843,089 to Sahatjian et al. (*The Sahatjian et al. Patent*). Claims 65 and 66 depend from claim 44 and thus for at least the reasons discussed in connection with that claim are novel and unobvious over the cited prior art. For example *the Silvestrini et al. Patent* fails to at least show a reactive material having a first state of protonation

prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body as claimed in claim 44. Nor does *the Sahatjian et al. Patent* make up for this deficiency. Thus, for at least these reasons *the Silvestrini et al. Patent* and *the Sahatjian et al. Patent* fail to make obvious claims 65 and 66.

Claims 92-94 are rejected under 35 U.S.C. Section 103(a) as being obvious by U.S. Patent No. 5,234,456 to Silvestrini (*The Silvestrini et al. Patent*) in view of U.S. Patent No. 6,060,543 to Ronan et al. (*The Ronan et al. Patent*). Claims 92-94 depend from claim 89 and thus for at least the reasons discussed in connection with that claim are novel and unobvious over the cited prior art. For example *the Silvestrini et al. Patent* fails to at least show a stimulus-expandable hydrogel having a first state of protonation prior to implantation in the body and undergoing a change to a second state of protonation after implantation in the body as claimed. Nor does *the Ronan et al. Patent* make up for this deficiency. Thus, for at least these reasons *the Silvestrini et al. Patent* and *the Ronan et al. Patent* fail to make obvious claims 92-94.

IV. DOUBLE PATENTING

Claims 44-47 and 69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting in view of claims 1-5, 7, 17, 20 and 22 of copending application number 10/763,975. Claims 1-5, 7, 17, 20 and 22 have been canceled in the '975 application. Therefore it is requested that the provisional double patenting rejection be withdrawn.

V. ALLOWABLE SUBJECT MATTER

The undersigned acknowledges the allowance of claims 81-85 and 95-98 and the indication of allowability of claims 99 and 100 if rewritten to overcome the rejection under 35 U.S.C. Section 112.

VI. MISCELLANEOUS AMENDMENTS

Claims 44 and 89 have also been amended to correct typographical errors.

Applicant: Brian J. Cox
Serial No.: 09/909,715
Art Unit: 3731

PATENT
Atty Docket: 388700-57A

VII. WITHDRAWN CLAIM

Claim 59 depends from claim 44 and remains withdrawn in this Amendment. However, upon allowance of generic claim 44 it is requested that the withdrawal status of claim 59 be removed and the claim allowed.

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Atty Docket: 388700-57A

CONCLUSION

In view of the foregoing, it is submitted that pending claims 44-47, 54-56, 59-61 and 64-69, 76, 77, 81-85 and 87-100 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



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